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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,043	12/01/1998	DANUTA EWA IRENA MOSSAKOWSKA	88362/104	1645

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/142,043	MOSSAKOWSKA et al.
Examiner	**Art Unit**
Fozia Hamud	1647

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 8, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *37-57* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *37-57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 December 2001 in Paper No:24 has been entered.

Claims 37-44, 48, 52-54 and 57 have been amended. Claims 37-57 are pending and under consideration.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2a. Claims 37-42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 37 recites "A polypeptide comprising...." which encompasses the polypeptide it occurs in nature. However, since Applicants do not intend to claim a naturally occurring product amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claim 37 be amended to recite " an isolated polypeptide comprising .....". Appropriate correction is required.

Claims 38-42 are rejected in so far as they depend on claim 37 for the above cited limitation.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 37-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 37-57 contain new matter language which was not disclosed in the instant specification as originally filed. Claims 37, 43, 48, 52-54, all recite ".....wherein the polypeptide **does not comprise a mature short consensus repeat-3**", which is new matter recitation. Applicants have pointed out to specific page and line numbers in the instant specification where support for said recitation is to be found, for example, page 17, lines 31-35, page 19, lines 14-20, page 20, lines 31-35 and page 21, lines 20-24. However, while the exemplified pages disclose specific fragments of the short consensus repeat-3 (for example E1 (c154-c174 to E5 (F164-G186), no support was found for the negative limitation added to the amended claims, i.e, "....wherein the isolatd polypeptide does not comprise a mature short consensus repeat-3", anywhere in the instant specification including the pages that Applicants have pointed to having support for said recitation.

Therefore, the negative limitation recited in instant claims 37, 43, 48, 52-54 do not meet the written description provision of 35 U.S.C. 112, first paragraph, because this was never disclosed in the specification as ordinally filed, as such it introduces new matter into the claims. Claims 38-42, 49-51, 55-56 are also rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on claims 37, 43, 48, 52-54 for the above limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 37-42, 44, 48 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claim 37 recites the limitation "....., wherein the isolated polypeptide...." in line 5. There is insufficient antecedent basis for this limitation in the claim.

4b. Claims 42 is indefinite for reciting the phrase ".....wherein the polypeptide is altered to remove chemically reactive amino acids", which chemically reactive amino acids should be altered, all of them, some of them? Appropriate correction is required.

4c. Claims 49 recites "...wherein the host protein contains at least one SRC repeat", however, it is unclear which SRC repeat . Appropriate correction is required.

4d. Claim 48 recites "...wherein polypeptide is inserted in a region of the host protein ...", this renders the claim vague and indefinite, Applicants should recite the specific region of the host protein wherein the polypeptide of the invention is supposed to be inserted.

Claims 38-39 and 41 are rejected under 35 U.S.C. 112, second paragraph insofar as they depend on claim 37 for the limitations set forth in paragraph 4a of this action.

Claim rejections-Double patenting

Non-statutory double patenting rejection (obviousness-type)

5a. The rejection of claims 37, 51 and 57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 10 of U.S. Patent No. 5,833,989, is maintained for reasons of record set forth in the previous office action, (Paper NO:15, mailed on 27 April 2001), page 3.

Claims 37, 51 and 57 still use the open language "comprise", therefore, the patented claims read on instant claims 37, 51 and 57, as was set forth in the office action of 27 April 2001, because of the open language used. Although the conflicting claims are not identical, they are not patentably distinct from each other. Instant 37, 51 and 57 are drawn to an isolated polypeptide comprising a 6 to 23 amino acid portion of SEQ ID NO:1 (with selection for amino acid 6-11 or 11-20 of SEQ ID NO:1), a SCR3-derived polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 4, 5, 7 and 8, and a pharmaceutical composition comprising polypeptide comprising a 6 to 23 amino acid portion of SEQ ID NO:1, respectively. Claims 2 and 10 of U.S. patent NO.5,833,989 (having two common inventors with the instant application), claim a soluble polypeptide comprising no more that one short consensus repeat (SCR) of long homologous repeat A of complement Receptor 1 (CR1), wherein the polypeptide comprises SCR3 and a pharmaceutical composition comprising said polypeptide. The SCR3 claimed in the parent comprises amino acid residue 125 to amino acid residue 191 of the CR1 which consists of 253 amino acid residues. Instant SEQ ID NO:1 comprises amino acid residues 155-187 of SCR3 sequence, therefore, instant claims 37, 51 and 57, are species to claims 2 and 10 in the patent which encompass the subject matter of the instant claims. The instant claims are obvious from the patent claims because the patent is directed to genus subject matter in which the instant claims are one specific

embodiment. The instant claims are included in the patented product. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a soluble polypeptide comprising no more than one short consensus repeat (SCR) of long homologous repeat A of complement Receptor 1, wherein the polypeptide comprises SCR3, includes an SCR3-derived polypeptide, because the term "comprising" in the instant claims denotes open language, encompassing the patented claims. The instant claims if infringed upon would also result in infringement of the broad claims of the patent. Allowance of the pending claims, therefore, would have the effect of extending the enforceable life of the allowed claims beyond statutory limit. Applicants have amended claims 37 and 57 to recite "...wherein the polypeptide does not comprise a mature short consensus repeat-3", however, this is new matter and therefore, does not overcome the double patenting rejection. As was repeatedly suggested using the closed language "consisting" would obviate this rejection.

Claim rejections-35 USC § 102

A person shall be entitled to a patent unless --

> *(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

6a. Claims 37, 39 and 51-57 are rejected under 35 U.S.C *§ 102*(b) as being anticipated by Fearon et al (U.S. WO 91/05047).

Fearon et al teach an isolated human complement receptor type 1 (CR1) protein and fragments thereof (see claims 41-52), polynucleotides encoding said CR1 protein and fragments, recombinant expression vectors comprising said polynucloetides and host cells transformed with

the expression vector (see claims 1-29), a pharmaceutical composition comprising the CR1 protein, and methods of producing the CR1 protein recombinantly and by chemical synthesis, (see abstract, page 9 , lines 1-20).

Claims 37, 39 and 51-57 of the instant Application are drawn to an isolated polypeptide comprising a 6 to 23 amino acid portion of SEQ ID NO:1, wherein the polypeptide is selected from the group consisting of amino acids 6-11 and 11-20 of SEQ ID NO:1, polynucleotide encoding said polypeptide, an expression vector comprising said polynucleotide, a host cell comprising the expression vector, a pharmaceutical composition comprising said polypeptide, and methods of producing the polypeptide recombinantly and by chemical synthesis. The CR1 protein disclosed by Fearon et al comprises amino acids 1-253, of which amino acid 125-191 represent SCR-3. Instant SEQ ID NO:1 comprises amino acids 155-187 of the CR1 protein sequence, which is embedded in the CR1 sequence disclosed by Fearon.

Therefore, Fearon et al reference clearly anticipates claims 37 and 51-57 of the instant Application, because, Fearon et al disclose SEQ ID NO:1, claimed in the instant application. With respect to claim 39 which is directed to SCR3-derived polypeptide further comprising a chemically reactive amino acid residue at the carboxyl and amino termini, all amino acids are considered to be chemically reactive, therefore, the CR1 protein disclosed in Fearon et al reference anticipates this claim as well.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7a. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fearon et al (WO 91/05047) in view of Capon et al (U.S. Patent 5,116,964).

The teachings of Fearon et al have been set forth above, however, Fearon et al do not teach a chimeric polypeptide comprising a host protein and an SCR3-derived polypeptide.

Capon et al teach chimeric polypeptides comprising ligand binding partners fused to stable plasma proteins which is capable of extending the in vivo plasma half-life of the ligand binding partner, (see abstract and column 5, lines 14-20).

Therefore it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to produce chimeric protein comprising a plasma protein and a polypeptide comprising a portion of the human complement receptor type 1 (CR1) because, Capon et al teach that chimeric polypeptides comprising a plasma protein and a polypeptide of interest are more stable and have extended in vivo half lives.

One of ordinary skill in the art would have been motivated at the time of the invention to produce chimeric protein comprising a plasma protein, and a polypeptide comprising a fragment of CR1 because, polypeptides corresponding to portions of CR1 possess complement inhibitory activities and are active in the complement system to aid in the removal of foreign substances from host animals.

conclusion

8. No claim is allowed.

Art Unit: 1647

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wedensday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
05 March 2002

Yvonne Eyler

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